

ANDERSON EXHIBIT 33

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

THIS DOCUMENT RELATES TO:

*United States of America ex rel. Ven-a-Care
of the Florida Keys, Inc. v. Abbott
Laboratories, Inc.*, Civil Action No. 07-
11618-PBS;

MDL No. 1456
Master File No. 01-12257-PBS
Subcategory Case No. 07-11618 -PBS

Hon. Patti B. Saris

Magistrate Judge Marianne B. Bowler

**DECLARATION OF MARK G. DUGGAN, PH.D., IN SUPPORT OF VEN-A-CARE'S
RESPONSE TO ABBOTT'S MOTION FOR PARTIAL SUMMARY JUDGMENT AND
IN OPPOSITION TO ABBOTT'S MOTION IN LIMINE**

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I, Mark G. Duggan, hereby declare as follows:

1. I am a Professor in the Department of Economics at the University of Maryland, College Park, Maryland. However, at this time and continuing through the 2009-2010 academic year, I am on leave to work on national health care policy as the Senior Economist for health care on the White House Council of Economic Advisers.

I. QUALIFICATIONS

2. I received my Bachelor of Science in Electrical Engineering from M.I.T. in 1992, and my Master of Science in Electrical Engineering from M.I.T. in 1994. I obtained my Doctorate in Economics from Harvard University in 1999. I was an Assistant Professor in the University of Chicago's Department of Economics, and a Visiting Assistant Professor in M.I.T.'s Department of Economics before joining the University of Maryland's Department of Economics in 2003.

3. I was awarded a two-year Alfred P. Sloan Foundation Fellowship in 2004, an award that is made each year to only six to eight economists who are selected from those in the entire profession who are within six years of receiving their Ph.D. I have served on several committees at the University of Maryland and have received teaching and/or advising awards at Harvard University, M.I.T., the University of Chicago, and the University of Maryland. I have served as an advisor to approximately 20 Ph.D. students at the University of Chicago and the University of Maryland, with my recent advisees accepting positions at major universities and the World Bank.

4. My professional activities include serving as a Research Associate at the National Bureau of Economic Research in the Health Care and Public Economics programs. I was also recently a Visiting Fellow at the Brookings Institution and I am a member of the American Economic Association and the American Society of Health Economists. I serve as an Associate Editor of the *Journal of Public Economics* and on the Board of Editors of the *American Economic Journal: Economic Policy*. I have been the Principal or co-Principal Investigator on

numerous research grants, including current ones from the National Science Foundation and the Social Security Administration. The National Science Foundation grant is for a project with Fiona Scott Morton, Ph.D., to explore the effect of the Medicaid program on the price and availability of pharmaceutical treatments to the 52 million individuals currently insured by the program.

5. I have published more than a dozen papers and have presented my research at numerous professional conferences and at dozens of academic institutions including Columbia University, Harvard University, M.I.T., Princeton University, Stanford University, University of Chicago, and Yale University. One paper I published was the lead article in the January 2005 issue of the *Journal of Health Economics* and was titled *Do New Prescription Drugs Pay for Themselves? The Case of Second Generation Antipsychotics*. Another recent paper, jointly authored with Dr. Scott Morton, was titled “The Distortionary Effects of Government Procurement: Evidence for Medicaid Prescription Drug Purchasing” and was published as the lead article in the February 2006 issue of the *Quarterly Journal of Economics*. A more recent paper on the Supplemental Security Income program, jointly authored with my colleague Melissa Kearney, Ph.D., and published in the Autumn 2007 issue of the *Journal of Policy Analysis and Management*, received the Raymond Vernon Memorial Prize for being voted the best research article in that journal in 2007.

6. Other papers I have published focus on the Medicaid and Medicare programs and have been published in some of the leading journals of my profession, including the *Journal of Public Economics*, the *Quarterly Journal of Economics*, the *Journal of Economic Perspectives*, and the *RAND Journal of Economics*. I have published empirically-oriented papers on other topics in leading journals including the *American Economic Review*, *Forum for Health Economics and Policy*, *Journal of Economic Perspectives*, *Journal of Political Economy*, *Journal of Policy Analysis and Management*, and the *Journal of Public Economics*. In two of my current projects, I am analyzing the impact of Medicare Part D on pharmaceutical prices

(with Dr. Scott Morton) and the effect of consolidation in the health insurance industry on health insurance premiums (with Leemore Dafny, Ph.D., and Subramaniam Ramanarayanan, Ph.D.).

7. My research is empirically oriented and focuses on the impact of government expenditure programs such as Medicaid, Medicare, and Social Security. I have conducted several studies in which I apply advanced quantitative methods to large-scale data sets to investigate questions in applied microeconomics that are of interest to academics and policymakers. A central issue in most of these studies is determining whether a causal relationship exists between one variable and another. For example, in my *Journal of Health Economics* paper on pharmaceutical treatments, I investigate the impact of certain new treatments on Medicaid spending and health outcomes.

8. Much of this work has included the aggregation of highly complex encounter-level data to the individual level, which is then often merged with other data. For example in a paper published in the *Journal of Public Economics*, I aggregate Medicaid claims and expenditure data to the individual level and then merge this with data on individual-level HMO enrollment. Similarly in current research on Medicare Part D with Dr. Scott Morton, I am utilizing encounter-level data from the Medical Expenditure Panel Survey to estimate the Medicare market share for every one of the top 1,000 drugs in the United States.

9. In carrying out research, I have followed the methods that are generally applied and accepted in my profession to ensure that the data sets that are constructed are accurate and reliable. I have then applied the most appropriate microeconomic methods to investigate causal relationships. For example, in the *Journal of Health Economics* paper referred to above, I used instrumental variables methods to estimate the effect of new pharmaceutical treatments on Medicaid expenditures. In a *Journal of Public Economics* paper on Medicaid managed care, I used a differences-in-differences methodology that exploited the differential timing of county-level Medicaid managed care mandates to estimate the effect of HMOs on Medicaid expenditures. And in a *Quarterly Journal of Economics* paper, my co-author and I estimated

multivariate regression models that were grounded in economic theory to estimate the effect of Medicaid market shares on pharmaceutical prices.

10. I was retained as an expert by Ven-A-Care to apply my expertise in analyzing large scale data sets and using econometric methods, as I do in my academic work described above, to compute damages in this case. I understand that this declaration will be used by the relator in connection with briefing in this case.

11. My prior work in these average wholesale price (AWP) cases involved preparing expert reports, including supplemental and rebuttal reports. I understand that some of my expert reports have been appended to the papers filed by defendants. The statements in my reports and my deposition testimony given in these cases are accurate and I would testify under oath consistently with the statements I have made in the reports, depositions, and in this declaration.

II. MEDICAID DATA USED IN MY DAMAGES CALCULATIONS

A. Medicaid Claims Data

12. There seems to be considerable confusion by defendants over the claims data that I have used in my analysis, and it has been misrepresented in various ways by defendants. My analysis relies upon two main categories of Medicaid claims data. One category is data that was collected directly from the states in connection with this litigation. The other data was collected by the Centers for Medicare and Medicaid Services (“CMS” formerly the Health Care Financing Administration (“HCFA”)) directly from the states in connection with CMS’ administration of the Medicaid program. The data collected from the states by CMS is of two types. One is known as the State Drug Utilization Data (“SDUD”). The other category includes three similar types of data known as the Medicaid Analytic Extract (“MAX”) data, the State Medicaid Research Files (“SMRF”) and the Medicaid Statistical Information System (MSIS). This data is similar and is generally referred to together as SMRF/MAX or SMRF/MAX/MSIS. The combination of the datasets provided me with claims data from all 50 states.

1. Claims Data Collected Directly from State Medicaid Agencies

13. The collection of claims data directly from state Medicaid agencies was an ongoing process pursued to some extent by both the United States and by defendants. It is my understanding that any data initially acquired by the United States was made available to defendants and vice versa. In total, data was acquired directly from over 30 states which covered at least part of the claims period at issue in this case.

14. The data collected directly from the states generally contained a high level of detail. Thus, it included the information on a claim by claim basis and usually (but not always) included a breakdown of the ingredient cost and dispensing fee, as well as other related claims information.

2. SMRF/MAX/MSIS Data

15. CMS itself collected a large amount of Medicaid claims data directly from the states which is referred to as SMRF/MAX. The MAX data, which is the current version of the data is described by CMS as “a set of person-level data files on Medicaid eligibility, service utilization, and payments.” Similar data for prescription drug claims are also available for 30 states in one or more years from 1991 through 1998, with the data referred to as the State Medicaid Research Files (SMRF) during this earlier period. The SMRF/MAX/MSIS data is claims level data with over 40 data elements including, for example, the NDC, the date of service, the charged amount, the paid amount, the date of the payment, and the quantity. SMRF-MAX and MSIS provide the specific amount billed and paid (rounded to the nearest dollar, but since it is reasonable to expect that half are rounded up and half are rounded down it is unlikely for there to be any material impact).

3. SDUD Data

16. CMS also collected the SDUD data from the states. This data provides detailed information about drugs dispensed by pharmacies and reimbursed on an NDC basis by the Medicaid programs of each state, including the total number of prescriptions filled and the total

amount paid for each NDC in every quarter. This information on NDC-state-quarter-specific Medicaid spending and utilization for the 1991 through 2007 time period is publicly available on the CMS website. The SDUD data is “aggregate” data and does not provide detail for each individual claim in the manner provided by the data collected directly from the states and the SMRF/MAX/MSIS data.

B. Validation and Use of the Data

17. For various reasons, including need, timing, and resources, I did not perform a claim by claim analysis of all of the data collected from the individual states. However, I did use the data from the additional states in other ways, for example, to help evaluate which were the best states to include in the claim by claim analysis, and to help validate the SMRF/MAX/MSIS/SDUD data. The various datasets, when used in combination, also help to calculate the basis of the claims when doing so with one database was not possible. Forgoing the use of data is a common and accepted practice in economics and econometrics and doing so in this case did not adversely affect my analysis. Thus, for my Medicaid analyses, I utilized claims data obtained directly from state Medicaid agencies for 15 states in my Abbott “Ery” analysis. The data from these states accounted for approximately 70 percent of the total dollars paid for the Abbott “Ery” drugs named in the Complaint. The reason that they account for such a large share of claims is that I endeavored to perform the most detailed analysis on the state claims data for the states with the largest number of claims. The remainder of my analysis relied upon the data collected from the states by CMS. The use of these various datasets in combination allowed me to calculate the basis of the payment for the claims with a high level of precision.

18. As noted above, the claims data collected directly from state Medicaid agencies is extensive and accounts for between 70 percent of the total dollars paid for the Abbott Ery drugs named in Ven-a-Care’s Complaint. The SDUD and SMRF/MAX data pertained to varying time periods for all 50 states plus the District of Columbia, and overlapped substantially with each other and with the data obtained directly from the states. The overlap in the data sets allowed me

to validate the accuracy of each data set through a review and comparison of each so that only data determined to be reliable was utilized. Although there were differences between the datasets, the reasons for the differences was discernible and could be appropriately accounted for in my analysis. I found no material variations between the datasets.

19. I never calculated any damages except where I had data that was based upon claims submitted to the state Medicaid programs which I had evaluated for reliability and concluded was reliable as was the case for detailed claims level data and aggregate data.. In order to further improve upon the reliability of my results, I performed various reviews. For example, I checked each claim contained in the data acquired directly from the states to verify its accuracy by seeing if I could replicate the amount paid. Data that was found to not match a state's methodology, or that was otherwise questionable was not used in my analysis. As a result, I discarded large amounts of data that likely would have increased the calculated damages.

III. BASE DAMAGE CALCULATIONS

A. Average Selling Prices

20. In general, to calculate the average selling prices of Abbott's Ery drugs, I simply divided the sum of total sales and chargebacks (if applicable) for each NDC by the sum of the total quantity. I performed that calculation for each NDC and quarter from 1994 to 2008.

21. I calculated these average prices paid for indirect sales to pharmacies as well as direct sales to wholesalers.

22. I also calculated the prices at the upper 95th percentile of the distribution of prices for the same quarters and years.

B. Medicaid Damages Methodology

23. My expert reports lay out the manner in which I examined the data collected directly from the 15 states which I will summarize briefly.

24. My approach where I analyzed the data collected directly from a state was similar across states. First, I examined the data itself to confirm that it was reliable and within the scope of the case. I performed this review for all of the 15 states for each defendants' NDCs and made all necessary adjustments.

25. The next step I took for each state was to examine its adjudication formula.

26. In virtually all states the scaled AWP was sometimes compared with an FUL (federal upper limit) or SMAC (state maximum allowable cost). This would typically occur if a product had an FUL and/or SMAC in effect and either one of them was lower than the scaled AWP. In these cases the algorithm was the same, except that the scaled AWP would be replaced by the FUL or the SMAC.

27. I then compared the adjudication formula to the actual claims data. For example, I often found claims that had a paid amount that was equal to zero. I also checked the claims to see if I could replicate the amount paid. Thus, I would identify claims for which I was unable to replicate the amount paid or where there appeared to be some data error such as an implausibly large dispensing fee. I excluded all such claims from my analysis sample. I did this review for each state.

28. I then linked each claim to the NDC-quarter-specific average prices described in the preceding sections to determine how the use of alternative values for the AWP would have affected state Medicaid spending. In other words, I took the average prices I had calculated from the defendants' transaction data, scaled it up by 25%, and then substituted that price in place of the AWPs that were actually published in the First Databank data and used by the state in the adjudication of the claims. Any necessary WACs and Direct Prices were replaced in a similar fashion.

1. Application of the "Lower of" Methodology

29. In some cases, I was aware that the states may have added another price parameter to their reimbursement algorithms in addition to AWP, WAC, Direct Price or U&C.

For example, some states added a ceiling price known as a Maximum Allowable Cost (“MAC”) or a Federal Upper Limit (“FUL”) for one or more Complaint products at some time during the period of interest. In these cases, the published prices, AWP, WAC, or Direct Price, continue to be used in the reimbursement logarithm, but in almost all cases they were also compared to the MAC or FUL to see which is lower.

30. In the application of the adjudication methodologies from the various states, my analysis only produced a damages figure in circumstances where the reporting by defendants of prices based on the averages I calculated would have caused the state to reimburse the claim in a lower amount. My methodology effectively “re-adjudicated” each of the claims in the same manner as would have been done by the state in the first place had these more accurate average prices been reported by Abbott for the Ery drugs and then utilized by the states.

31. With rare exceptions, each state’s adjudication methodology employed a “lower of” logic such that a defendants’ price that was higher than any alternative price would cause the lowest of the alternative prices (i.e., SMAC or U&C) to be selected. In contrast, a price from defendants that was lower than any alternative price would cause defendants’ price to be selected. Thus, if defendants’ AWP, when scaled in accordance with the applicable state methodology (i.e. AWP - 12%) resulted in a lower amount than any potential alternative price, it would be used as the basis of payment, and the alternative prices would not be used. Concomitantly, if defendants’ AWP, when scaled in accordance with the applicable state methodology (i.e. AWP - 12%) resulted in a higher amount than any potential alternative price, the alternative price would be used as the basis of payment, and the defendants’ scaled AWP, although used as part of the logarithm to decide which price would be used as the basis of payment, would not directly be used as the basis of payment.

32. A rare exception to the “lower of” approach is found in New York which did not have a MAC program, but did use FULs without comparing them to see if they were lower than other potential alternative prices. These Try products did often have FULs. For this reason, I

accounted for the New York exception by simply not calculating damages for New York in any case where an FUL was in effect. This decision also caused my subsequent extrapolations to other states to be very conservative and decrease calculations of reimbursement differences in payments. New York is a very high-utilization Medicaid state. The calculation of no damage in all instances where New York paid based upon a FUL was pro-rated to the other 34 states. This underestimated the damages in those states because almost all of them did not follow New York's unique method of paying strictly a FUL.

2. Outcome for the 15 States

33. In general, I found that defendants' actual published prices changed the outcome of the adjudication methodology in a very large percentage of the claims for each of the states. Although the higher amount paid by a state may have in some cases been limited by a MAC or the actual charge of the provider (ie., U&C) to an amount less than Abbott's scaled AWP, the reason the MAC or the actual charge would have been used was the inclusion of Abbott's inflated published price in the adjudication methodology. Where the replacement of Abbott's inflated published prices with lower actual average transaction prices results in lower reimbursement, then I calculate a difference for these 15 states. These differences amount to millions of dollars for these 15 states. After extrapolating to the remaining minority of claims in the smaller states, I determined the federal share of Medicaid overpayments to be \$15.559 million across all states.

IV. EXTRAPOLATION

34. Extrapolation is simply described as a way to estimate by projecting known data. Extrapolation is a useful tool used by economists even if complete and perfect data exists. This is the case because use of all data is often time consuming or prohibitive and unnecessary. There are acceptable methods of extrapolation and I have used them in this case.

35. An economist is normally faced with the challenge of applying quantitative or statistical methods to data and data sets that are often incomplete, non-comprehensive, or

imperfect. In fact, the need for an economist is often driven by the lack of sufficient quantitative information. Economists have and use tools in practical applications and in academic research to adjust for incomplete or imperfect data. Those tools include but are not limited to econometrics, statistical sampling, and extrapolation. Such tools are aided by econometric, statistical, and mathematical software. These same tools used in academic research can be used in calculating damages in cases in litigation. I have used these same tools in my academic research as well as the average wholesale price litigation in which I have been involved since approximately March 2006.

36. It has been brought to my attention that defendants have filed various motions claiming that my selective use of data sets undermines or invalidates the work I did on arriving at a reasonable estimation of damages in this case. This is incorrect and perhaps misleading. As explained above, I had various data sets for use. The fact that I did not have state-produced claims data for some states does not mean I did not have state claims data. As I explained above, CMS had state claims data collected from earlier state productions in a form different than the individual claims data provided by the states during the litigation. In fact, if states were unable or unwilling to produce in litigation their individual claims data, I still could have performed a reasonable estimate of damages in this case from the state data collected by CMS. Therefore, it is not correct to state or suggest that I did not have state claims data for all states.

37. I also understand that defendants have claimed that my use of extrapolation in these AWP cases was flawed. Specifically, I understand that defendants have said that the extrapolation is “inconsistent with basic statistical standards, they are subject to clear selection bias, and they are demonstrably unreliable.” These arguments are incorrect and I can show that they are incorrect. Some of this I explained at my depositions in the AWP litigation; however, since the questions at the depositions were controlled by defendants, I did not have the opportunity to fully explain my methods. I try to do that in this declaration.

A. Medicaid Extrapolation

38. I can state to a reasonable degree of economic certainty that my use of extrapolation in these cases arrived at a reasonable approximation of the damages, or difference between (1) what the federal government reimbursed for certain pharmaceutical products dispensed to Medicaid recipients during the relevant period, and (2) what the federal government would have reimbursed for the same drugs during the same time period if prices reflective of the actual prices at which defendants were transacting business had been reported by defendants.

39. I used claims data collected directly from state Medicaid agencies for the 15 states which account for approximately 70% of all Medicaid claims for the “Ery” drugs named in the Ven-a-Care Complaint.

40. As I described, for each of these 15 states, the states did not directly produce (to the United States in connection with the lawsuit) data for each and every claims for all of the drug products at issue. In those unique instances I used claims data that the states provided to CMS in connection with the normal operations of the Medicaid program, some of which was claims-level data and some of which was the type of aggregated data that I described above, to fill in these modest gaps in actual state-produced claims data. Aggregated data describes high-level data that is composed of a multitude or combination of other more individual data. The use of such aggregated data does not diminish the reliability or validity of the damages estimate I calculated. As an economist, I am trained in methods of using aggregated data when individual data is unavailable or prohibitive and unnecessary, all of which was true in this litigation.

41. For the remainder of the states, I used the information regarding the 15 states as the basis for estimating the additional damages. The extrapolation from the 15 states to the other states was reasonable for at least the following reasons. First, I extrapolated only to those periods for which I had claims data that I found to be reliable. Second, I used data for more than one thousand combinations of NDC quarters when estimating the damages associated with the other states.

42. Third, for the 15 states, I ran my analysis on a claim by claim basis. My extrapolations were based on my detailed analysis of this large proportion of the overall claims. As I stated, the 15 states accounted for almost 70% of the total dollars paid for the defendants' Complaint NDCs and my methodology allowed me to re-adjudicate each of those millions of claims. As an economist, I found this method to be more appropriate than other methods I could have used. This was a better method than a traditional random sample, which would have been a review of a much smaller fraction of those claims. This was also a better method than sampling each NDC for each state for each year which could have required thousands of separate samples with numerous sample claims in each sample; such an approach would have been near impossible and fewer claims would have been reviewed.

43. Fourth, in many circumstances I had detailed state data and other aggregated data described above for the same time periods. When I compared data obtained directly from the states to this other data, I found the aggregated data or CMS data was reliable because there were few significant variations between the two because the total dollars and units generally matched, and all of the variations were accounted for.

44. Fifth, I examined all of the data which I relied upon to assess its quality. For example, I reviewed every claim in the data collected from the states to confirm that I could replicate the amount paid. This was a detailed review. I did not use data in my analysis if I found it unreliable. In the other case against Abbott, I found the Indiana data to be unreliable so I did not use it.

45. Sixth, I had state claims data from over 30 states which covered at least part of the relevant time period, and I performed a general review of this data to confirm that it was consistent with my other findings. I chose not to use all of the state data in my possession to perform detailed claim by claim calculations because it was prohibitive or duplicative and unnecessary.

46. Seventh, by focusing on the 15 states, I was able to perform a higher quality review of the state claims data which served as the basis for the extrapolation. The state pharmacy reimbursement methodologies for the 15 states were very similar to the state pharmacy reimbursement methodologies for the other states.

47. Eighth, the average amounts paid¹ for each NDC by the 15 states were very similar across those 15 states. The average amounts paid for each NDC by the 15 states were also very similar to the average amounts paid for each NDC by the other states.

48. Ninth, I eliminated a substantial number of claims which did not precisely match the expected reimbursement and the damages on those claims were assumed to be zero even though it is likely that there were some damages associated with those claims. Finally, I made numerous downward adjustments in the scope and magnitude of my extrapolations that would much more than offset the magnitude of any differences between the 15 states and the other states.

1. The Nature of the Medicaid Extrapolations

49. It is my opinion that a reliable estimate of the total damages to the United States can be based on the data collected directly from the 15 states which represent almost 70% of all the claims at issue, together with the data collected from the states by CMS for the other states.

50. As I calculated the damages in this case, I performed many different tests to confirm that the data was suitable for the purposes at hand. Thus, there were numerous checks done to confirm that each of the data sets was reliable and could be used in the manner that I used them. The numerous checks that I performed on the data are described throughout the following analysis and in my expert reports.

51. The nature of the extrapolations which I performed in this case have been fundamentally misconstrued by the defendants and their experts who criticize my extrapolations. They posit that extrapolations can only be done in connection with routine random samples, or

routine disproportionate random stratified samples of the type typically done when examining the claims of a single provider over the course of a single year. Samples are used because it is normally impossible to examine an entire population. Thus, researchers select a sample of the population, and use the information learned during the examination of the sample as a basis for predicting the nature of the entire population. Of course, it is important that the sample be representative of the entire population, and not be biased in any systematic fashion. The typical way to select a representative, non-biased sample is through randomization. However, a sample can still be representative and non-biased even if not selected through a random process.

52. The 15 states are not a random sample of the entire universe of 50 states. I chose to focus on the largest states to obtain the maximum amount of precision. Put simply, it is more important to the total value of the damages to be as accurate as possible for the state of Florida, than it is in the state of Vermont.

53. In addition, it is extremely important to note, as is shown throughout my analysis, the 15 states are fairly representative of the other states. My extrapolation methodology was strengthened by specific data from the states that were the subject of the calculations to ensure that damages nationwide were reliable and, if anything, understated, rather than overstated.

54. One quite simple, but significant component of the extrapolation that I have done (as is true for any extrapolation) is that it is based on averages. Thus, assuming you have done the types of checks that I have done, the variables that would tend to raise the damages figures are balanced by the variables that would tend to lower the damages figures. On average, of course, the number is reliable. A criticism based solely upon cherry picking examples of the variables that would tend to raise the damages figures without factoring in the variables that would tend to lower the damages figures is not reliable. Rather, such biased criticism suffers from the exact same type of bias flaw that the defense experts allege to be the supposed problem with my analysis. A key difference is that my analysis considered both sides of the equation, whereas the Abbott's experts appear to only or primarily consider the side of the equation that

benefits Abbott. There are numerous examples throughout my analysis of adjustments that reduce the amount of the damages that I have calculated, and those adjustments more than offset any of the alleged shortcomings leveled by the defendants. In addition, defense experts' criticisms are leveled without the benefit of any actual quantification of the supposed impact, so they are unhelpful.

a. Intra-State Extrapolation

55. In certain periods for each of these 15 states, I did not have complete state claims data collected directly from the states. However, that data was generally very complete.

56. As necessary, I used the SMRF/MAX/MSIS and aggregate SDUD data from CMS to analyze the remaining claims in those states.

57. The advantage of using each state's own claims data when extrapolating to those NDC-quarters when I do not have state claims data is that these NDC-quarters will typically share the same adjudication methodology and provider characteristics as in the NDC-quarters for which I do have state claims data.

58. As a check on my approach on this issue, for each of the largest states for which I performed within-state extrapolations, I assumed for the sake of the calculation that the state Medicaid claims data started one year later than they actually did. I then utilized the SMRF/MAX/MSIS claims data if it was available and otherwise used the SDUD data to estimate the total value of the damages during these one-year periods. My findings indicate that the total value of the damages is actually substantially higher when I use the claims data collected directly from the states compared to when I extrapolated using the SDUD and SMRF/MAX/MSIS claims data. The fact that I did not have complete state Medicaid claims data collected directly from the states for the entire time period considered for these states reduced rather than increased the total value of the damages. My extrapolation therefore inured to the benefit of the defendant.

b. Inter-State Extrapolation

59. In connection with my extrapolation from the 15 states to the other states, I also performed various additional checks. As mentioned above, these states account for a disproportionately large share of all Medicaid claims for Complaint products. Additionally, my coverage with state claims data is most complete during those years with the highest number of Medicaid claims and Medicaid expenditures.

60. In considering the validity of the extrapolation, it is worth noting that the two groups of states share many common features. All of the states reimburse for the same defendants' Complaint drugs and all of the states are subject to the same federal regulations. All of the states use published prices when adjudicating claims and the vast majority of the states use the AWP. The fraction of states in the two groups that use the WAC is similar and the scaling factors for these prices are on average similar between the two groups. With rare exceptions, all of the states in the two groups have a "lower of" methodology.

61. Additionally, in general, the ratio of the damages to total Medicaid spending across the 15 states – despite the different adjudication methodologies – is stable. Thus, the fraction of claims with damages greater than zero and the ratio of damages to the total amount paid is quite similar across states, whether the state uses the AWP, the WAC, or the DP.

62. It is also important to remember that often in applied microeconomic research there is *no* data for those entities to which the extrapolation is being performed. However, in this setting I am utilizing multiple sources of detailed information regarding Medicaid claims for the Complaint products for those states to which I am extrapolating. Additionally, I do not extrapolate to any state or time period in which I do not have CMS claims data or SDUD data.

63. Furthermore, it is indeed common practice in applied microeconomic research to use data for a subset of the entire population when estimating the effect for the full population. For example, the seminal research on the effect of the unemployment insurance (UI) program, including work by Bruce Meyer that was published in *Econometrica* in 1990, utilized

administrative UI data for just 8 states to estimate the effect of the UI program on trends in the national labor market. Additionally, research by Drs. Adams, Gruber, and Newhouse published in the *Journal of Human Resources* in 1997 examined the effect of physician fee changes in Tennessee while using Georgia as a control to shed light on the effect of Medicaid physician reimbursement on the treatment of Medicaid recipients. Additionally, it is common practice in applied microeconomic research to use data for a sample that may not be fully representative to estimate results for the U.S. as a whole. For example, Gruber and Rodriguez in their 2007 *Journal of Health Economics* study have data for a sample of just one percent of all physicians, and the characteristics of these physicians differ substantially from the average physician in the U.S. Despite this, they adjust their estimates accordingly to arrive at estimates for the provision of uncompensated care by all physicians in the U.S.

64. When considering the algorithm that I use in my analysis, it is important to emphasize that I used data for up to 15 states which resulted in more than one thousand NDC-quarter combinations when I estimated the value of the difference for these same NDC-quarter combinations in each of the remaining states. My examination of the adjudication algorithms used by these states, their reimbursement per claim, and so forth indicated that they were indeed very similar to the other states.

65. The algorithm I used was very straightforward. I began my analysis of each of the other state's SMRF / MAX data by applying inclusion criteria analogous to those described above for the 15 preceding states. For example, I dropped claims with a paid amount of zero or with a strictly positive third party payment amount. I then aggregated the number of claims and total Medicaid spending for each state by NDC-quarter.

66. I then merged this claims data for each of the remaining states to a data set in which the unit of observation was the NDC-quarter and that was constructed using the 15 states' Medicaid claims data described above. For each NDC-quarter, I first calculated the average fraction of claims with a difference greater than zero across all 15 states. I also calculated the

average value of the ratio of the difference to the amount of Medicaid spending on these claims. In calculating these averages, I weighted each of the 15 states that had data for that NDC-quarter equally, while states with no claims data for that NDC-quarter have a weight of zero. These averages then were used in my algorithm. I followed a similar algorithm for the SDUD data. Specifically I multiplied the number of claims in each state-NDC-quarter by the percentage of claims with a difference greater than zero to estimate the number of claims with a difference greater than zero. Similarly, I multiply Medicaid spending in the state-NDCquarter by the average value of the ratio of the difference to the amount of Medicaid spending on these claims.

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

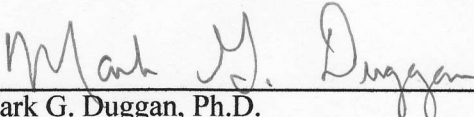
Executed this _____day of October, 2009.

Mark G. Duggan, Ph.D.

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I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 29th day of October, 2009.



Mark G. Duggan, Ph.D.